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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,670	10/02/2000	George H. Scherr		4775

7590

04/07/2004

George H Scherr Ph D
33 Monee Road
Park Forest, IL 60466

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/07/2004

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/676,670

Applicant(s)

SCHERR, GEORGE H.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/7/03, 9/24/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-149 is/are pending in the application.
- 4a) Of the above claim(s) 20-76 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 77-90, 105 is/are allowed.
- 6) ☒ Claim(s) 91-104 and 106-149 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. Pursuant to the Decision on the renewed petition under 37 CFR 1.137(b), filed on July 7, 2003, to revive the application and the subsequent Grant of said petition issued on September 24, 2003 from the Office of Petitions, Paper No. 12, the finality of the previous Office action is hereby withdrawn.

Status of the Claims and the Prosecution History

2. This Application is a CIP of 09/301,228 filed on April 29, 1999, that was abandoned on December 4, 2000.
3. The originally filed claims 1-54 were subject to a Restriction Requirement on January 29, 2002. Applicant elected claims 1-19 without traverse in Paper No. 3, filed on December 25, 2002.
4. Claims 20-76 were held withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention as being directed to such process with different modes of operation, and there being no allowable generic or linking claim. (see Paper Nos. 2, 4 and 6).
5. Claims 77-90 were declared allowable in Paper No. 6 filed on October 22, 2002.
6. Claims 91-104 were rejected under 35 U.S.C. 102(b) as being anticipated by Scherr US Patent 5,718,916 or Patel US Patent 5,470,576 in Paper No. 6 because claims 91-104 are drafted as "product by process" and Scherr and Patel were deemed to meet the limitations of claims 91-104 for the reasons of record set for in Paper No. 6, filed on October 22, 2002. The Paper No. 6 was issued as the Final Rejection on merits

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of then pending claims, because the rejection of record was necessitated by Applicant's amendment filed on July 12, 2002, Paper No. 5.

7. Claims 105-149 were then presented in Paper No. 7/B, filed on January 14, 2003 in response to the Paper No. 6 Final Rejection.

8. Claims 105-149 were properly not entered because Paper No. 7/B failed to reduce or simplify the issues for appeal. In addition, the amendment seemed to raise new issues.

9. Pursuant to the petition filed on July 07, 2003 and the Grant of said Petition on September 24, 2003, Paper No. 12, the application has now been revived and the finality of the Paper No. 6 is withdrawn. Claims 104-149 have been entered to merely simplify the status of the pending claims. Nevertheless, the issues remain the same as in Paper No. 6.

10. Claims 20-149 are pending. Claims 20-76 are withdrawn from consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention as being directed to such process with different modes of operation, and there being no allowable generic or linking claim. (see Paper Nos. 2, 4 and 6).

11. Claims 77-90 are free of art as declared allowable in Paper No. 6.

12. The newly added claims 105-123 are also free of art. However, claims 106-123 are now subject to a new ground of rejection under 35 USC 112, second paragraph as set forth below.

13. Claims 124-149 are also subject to a new ground of rejection under 35 USC 102 and 103(a) for the reasons set forth below.

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14. This communication is a Final Rejection, because all new grounds of rejection were necessitated by Applicant's Amendment in Paper No. 7/B, filed on February 4, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claims 106-123 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "viable" in claim 106 is a relative term which renders the claim indefinite. The term "viable" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. It is not clear what types of characteristics are required to ascertain the claimed cells viable. Common knowledge in the art suggests that when a suspension of cells is sterilized, the cells die and thus lose their viability.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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16. Claims 91-104 rejected under 35 U.S.C. 102(b) as being anticipated by Scherr US Patent 5,718,916 or Patel US Patent 5,470,576.

Claims 91-104 are drafted as "product by process." Accordingly, products by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps (see MPEP 2113).

Scherr discloses water insoluble alginate sponges (abstract, examples 6-8, col 11-12). Thus, Scherr anticipates the limitations of the instant claims.

Patel teaches the use of similar alginate compositions as wound dressings on absorbent pad or bandages by impregnating the with the alginate composition (see abstract, col 7, lines 4-60). Thus, Patel anticipates the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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17. Claims 91-104, 124-149 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakis US Patent 5,851,461 in view of Patel US Patent 5,470,576 and/or Scherr US Patent 5,718,916 .

Bakis teaches sodium or calcium alginate foams, pads or gauzes that can comprise at least an additional medicinal agent such as cells to be implanted in a human or animal body (see abstract, col 6, lines 35-67; examples 1-5). Bakis provides for fails to specifically enumerate various medicinal agents such as antibacterial, antibiotics or even the use of other di- or tri-valent alginate salts such as silver.

Patel provides that zinc alginate or silver alginates are well-recognized art equivalent tri-valent alginate salts that may be used in the art of sponge dressings. (see col 3, lines 14-26).

Scherr provides for incorporation of various sorts of medicinal agents such as antibacterial, antibiotics, etc.. into a topical surgical dressing, foam or sponge to improve therapeutic benefits. (see abstract, col 11, lines 2-10).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to add a suitable medicinal agent or use a suitable alginate salt in formulations of Bakis, because as shown by Patel, using art equivalent alginate salt, and/or further, as provided by Scherr, using a suitable medicinal agent in a surgical dressing to improve therapeutic benefits would have been an obvious modification of Bakis' dressings.

Conclusion

18. In conclusion, Applicant is reminded that cancellation of all product claims and overcoming the 112 2nd rejections towards claims 106-123 would render all process claims. At this time, claims 77-90, 105 are allowable.

19. In addition, Applicant is strongly advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

Applicant is advised of the availability of the publication "Attorneys and Agents Registered to Practice Before the U.S. Patent and Trademark Office." This publication is for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200